ATTACHMENT 4

K002465

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

Official Contact	David J. Vanella Manager, Regulatory/Product Assurance Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Phone: (724) 733-5866
Classification Reference	21 CFR 868.5905
Product Code	BZD – noncontinuous ventilator
Common/Usual Name	nasal mask
Proprietary Name	Respironics® Spectrum® 2 Full Face Mask
Predicate Device	Spectrum Full Face Mask (K961915)
Reason for submission	Modified design; modified materials.

Substantial Equivalence

The purpose of the design modification is to improve patient comfort and fit, and to improve ease of use. The modified mask has the following similarities to the previously cleared predicate device:

- ☐ Same intended use, environment, patient population.
- ☐ Same operating principle.
- ☐ Same technology.
- ☐ Same manufacturing process.

Design verification tests were performed on the Spectrum 2 as a result of the risk analysis assessment, and acceptance criteria were met. Respironics has determined that the modifications have no impact on the safety and effectiveness of the device. In summary, the mask described in this submission is substantially equivalent to the predicate device.

The modified mask complies with the applicable standards referenced in the "Draft FDA Reviewer Guidance for Premarket Notifications," November 1993.

Device Description/Intended Use

The Spectrum 2 Full Face Mask (Figure 1) is intended to provide a single-patient-use interface for adult patients (>30 kg) receiving Respironics CPAP or bi-level therapy. This is the **same intended use** as previously cleared for the Spectrum Full Face Mask (K961915).

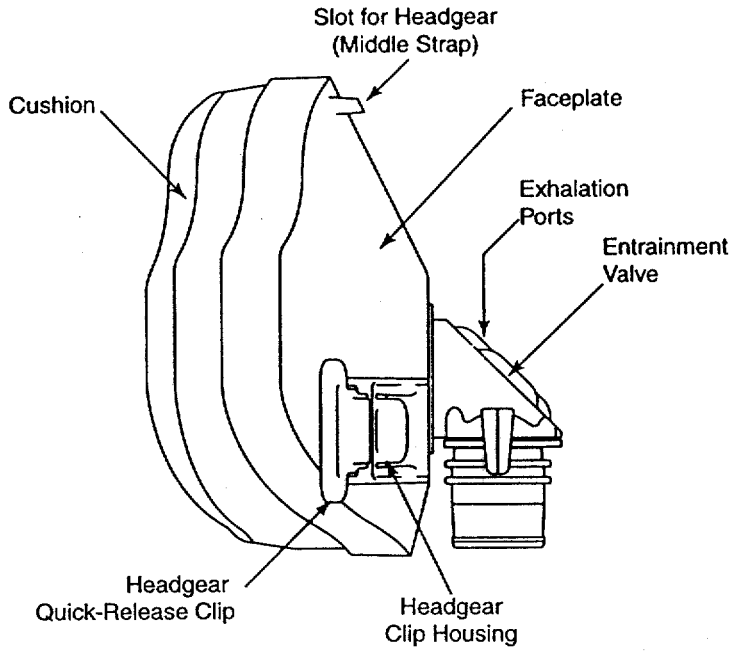

Figure 1. Spectrum 2 Full Face Mask (side view).

The mask fits over the nose and mouth. It consists of a polycarbonate faceplate and a silicone mask cushion. (Predicate faceplate materials are PVC and polyurethane, respectively). The device includes built-in exhalation ports and an entrainment valve that allows the patient to breathe room air if positive pressure is discontinued (e.g., power outage). Valve housing is polycarbonate. Valve flapper is made of silicone.

Thin cushion material allows two basic mask sizes to fit a broad range of facial structures. The mask contacts the nose at a point lower than between the eyes. Mask volumes are smaller than those of the predicate.

Faceplate has no pressure pickoff ports. Two headgear-clip housings are molded as part of the faceplate, one housing on either side. In addition, the slot at the top of the faceplate accepts the middle headgear strap. (Predicate's headgear slots are molded on either side of the cushion.)

The headgear is provided with two quick-release clips that attach to the clip-housings on the faceplate. The clip assembly has been designed as a built-in safety feature in the event the mask needs to be removed quickly. (The predicate headgear has a rip-cord design for quick release.)

Accessory Swivel snaps onto the entrainment valve tail. The swivel allows rotation of the patient circuit tubing. (Predicate mask's accessory swivel is provided from the Whisper Swivel exhalation device.) Tubing Quick Release allows accessory swivel to be released with the tubing (as one unit).

End of section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2000

Mr. David J. Vanella
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668-8550

Re: K002465
Spectrum 2 Full Face Mask
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: August 9, 2000
Received: August 11, 2000

Dear Mr. Vanella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002465

Device Name: Respironics® Spectrum® 2 Full Face Mask

Intended Use/Indications for Use

The Respironics® Spectrum® 2 Full Face Mask is intended to provide an interface for application of Respironics CPAP or bi-level therapy to patients.

Environment of Use/Patient Population

For single patient use in the home or hospital/institutional environment. The mask is to be used on adult patients (>30 kg) for whom CPAP or bi-level therapy has been prescribed using a Respironics CPAP or bi-level system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices

510(k) Number K002465